DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 20, 2015

Lite-Med, Inc.
Walt Hsu
President & CEO
9th Floor, 49 Dongxing Road
Xinyi District, Taipei City 11070
Taiwan

Re: K142561
Trade/Device Name: LM-9300 ELMA
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal shockwave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: December 22, 2014
Received: February 18, 2015

Dear Walt Hsu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4. Indications for Use Statement

510k Number: K142561

Indications for Use

510(k) Number (if known): K142561
Device Name: LM-9300 ELMA
Indications for Use:

The Lite-Med LM-9300 ELMA Lithotripter is indicated for fragmentation of kidney stones such as renal calyx stones and renal pelvic stones and for upper, middle and lower ureteral stones by extracorporeal shock wave lithotripsy (ESWL).

Prescription Use x AND/OR Over-The-Counter Use __ _
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5. 510(k) Summary

510k Number: K142561

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

LITE-MED LM-9300 ELMA Lithotripter

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the LM-9300 ELMA is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices, which includes the following: Lite-Med LM-9200 ELMA (K103217), Dornier Compact Alpha (K002929), and Siemens Lithoskop (K070665).

Applicant/Manufacturer Information

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Device Identification

Proprietary Trade Name: LM-9300 ELMA
Generic Device Name: Extracorporeal Shockwave Lithotripter
Product Code: 78 LNS
Regulatory Class: Class II with special controls
Regulation Number: 21 CFR 876.5990

Intended Use

The Lite-Med LM-9300 ELMA Lithotripter is indicated for fragmentation of kidney stones such as renal calyx stones and renal pelvic stones and for upper, middle and lower ureteral stones by extracorporeal shock wave lithotripsy (ESWL).

Substantial Equivalence

The Lite-Med LM-9300 ELMA Lithotripter is substantially equivalent to the following currently marketed devices:

Lite-Med LM-9200 ELMA (K103217)
Dornier Compact Alpha (K002929)
Siemens Lithoskop (K070665)

Device Description

The Lite-Med LM-9300 ELMA is an Electromagnetic Extracorporeal Shock Wave Lithotripter that effectively treats urinary calculi. It is routinely used for the fragmentation of kidney and ureteral stones and offers a good combination of clinical performance, flexibility and affordability. The standard LM-9300 ELMA system consists of a shockwave generator, an operator interface (industrial computer with dual monitors), a water circulation subsystem and a patient handling subsystem. For the Extracorporeal Shock Wave Lithotripsy (ESWL) operation to be fully functional, one or two more subsystems are necessary. The first is a C-arm X-ray fluoroscopy device and the second is an ultrasound imaging unit. Normally one of the imaging devices is sufficient. For most advanced ESWL designs such as LM-9300 ELMA both X-ray and ultrasound are used for patient positioning and monitoring purposes.

Shock waves are generated on the basis of a principle similar to that used in loudspeakers. An electrical impulse is sent through an inductance coil, generating a magnetic field which repulses a metallic membrane. The acoustic impulse created by this repulsion is focused by an acoustic lens to form a shock wave. A water circulation subsystem is used to provide transmission of shockwaves and cooling of the generator.

Technological Characteristics

The shock wave characteristics are reported below by taking the guideline described in the consensus standard IEC 61846 “Ultrasonics – Pressure pulse lithotripters – Characteristics of fields” (1998) into consideration. PVDF film type hydrophones are used in the measurements. The details of the measurements/calculations are given in relevant part of 510(k) application. The results are found similar to the predicate device characteristics.

Parameter	min(16kv)	typical(18kv)	max(20kv)
Peak-positive acoustic pressure(MPa)	24.7	41.1	46.9
Peak-negative acoustic pressure(MPa)	2.5	2.5	2.9
Rise time (ns)	400	200	100
Compressional pulse duration(ns)	400	400	360
Maximum focal width(mm)	5	5	8
Orthogonal focal width(mm)	5	5	8
Focal extent(mm)	90	90	90
Focal volume(mm3)	1178	1178	3016
Distance between the focus and target location(mm) –z-axis	3	3	3
Distance between the focus and target location(mm) –x/y-axis	2	2	2
Derived focal acoustic pulse energy density (mJ/mm^2)	0.23	0.48	0.78
Derived focal acoustic pulse energy(mJ)	1.48	3.19	7.05

Clinical Studies

The clinical investigations are performed at 2 sites with 1, 2, and 4 weeks follow-up to support this application. A total of 44 patients with 44 stones were treated. 31 patients were males and 13 patients were females. The stones sizes treated were between 5 mm and 16 mm. None of the patients received general anesthesia. The averaged stone-free ratio at one month after the stone treatments of the investigations is 80%. Among the investigations with residual fragments remained at 1 month after the treatments, more than half of the stone fragments are less than 5mm x 4mm in size. This means that the effectiveness of the LM-9300 ELMA Lithotripter is better than 90%.

Safety and Performance Studies

The LM-9300 ELMA is designed in accordance with the product safety and performance requirements established in the following standards given below:

IEC 60601-2-36	Particular Requirements for safety of equipment for extracorporeally induced lithotripsy
IEC 61846	Ultrasonics – Pressure pulse lithotripters – Characteristics of fields
IEC 60601-1	Medical Electrical Equipment – Part 1 General Requirements for basic safety and essential performance
IEC 60601-1-2	Medical Electrical Equipment – Part 1 General Requirements for Safety-2. Collateral Standard: Electromagnetic

	Compatibility-Requirements and Tests
ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971	Medical Devices – Application of Risk Management to Medical Devices
IEC 60601-1-3	Medical Electrical Equipment – Part 1 General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
IEC 60601-2-54	Medical Electrical Equipment – Part 2 Particular Requirements for the basic safety and essential performance of X-ray equipment for Radiography and Radioscopy

Conclusion

From a clinical perspective and comparing design specifications, the LM-9300 ELMA is substantially equivalent to its predicate devices. The LM-9300 ELMA meets the FDA requirements stated in "Guidance for the Content of Premarket Notifications 510(k) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi" issued on Aug. 9, 2000. Lite-Med Inc. believes the minor differences of the LM-9300 ELMA and its predicate devices should not raise any concerns regarding the overall safety or effectiveness.